



## **Annette M. Zinn, M.P.H., Ph.D., J.D.**

*Regulatory Counsel*

### **EXPERIENCE:**

- Regulatory Counsel, Private Practice 2008 to Present
- Regulatory Counsel, Regulatory Affairs Dept., Cyberonics, Inc.
- Adjunct Faculty, University of Houston, Bates College of Law
- Associate Attorney, Law Firm of Campa and Associates
- International Regulatory Advisor, Self-Employed Consultant
- Manager/Specialist, International Regulatory Affairs, Intermedics, Inc.
- Consultant/Epidemiologist

### **AREA OF EXPERTISE:**

*Devices:*

- Biocompatibility
- Cardiovascular
- Defibrillator/Monitor
- Disposable
- Electrodes
- Implants, active/non-active
- Material Suppliers
- Neurological
- Reusable Instruments
- Software
- Sterilization
- Therapeutic
- Urology

*Disciplines:*

- Regulatory submissions
- Legal (product liability, contracts, advertising/promotion)
- Animal studies and clinical trials
- Good manufacturing practice

### **TRAINING and CERTIFICATIONS:**

- FDA Workshop: GMP including HACCP, QSIT, design controls, complaint handling, audits
- Food and Drug Law Institute-Introduction to Medical Devices, Enforcement
- RAPS-Multiple conferences and workshops
- Risk analysis and management (complaint handling/root cause analysis)
- ISO 14971, ISO 13485



**EDUCATION:**

- Ph.D., Management & Policy Science, University of Texas School of Public Health, Houston, TX USA
- J.D., South Texas College of Law, Houston, TX USA
- M.P.H., University of Texas School of Public Health, Houston, TX USA
- B.S., University of Houston, Houston, TX USA

**AFFILIATIONS:**

- American Bar Association (Section: Administrative Law)
- Texas Bar Association (Sections: Administrative Law; Health Law)
- United States District Court, Southern District of Texas
- Food and Drug Law Institute
- Regulatory Affairs Professional Society
- American Public Health Association

**PUBLICATIONS AND PRESENTATIONS:**

- Effects of Congressional Modernization Laws on Public Access to Innovative (Class III) Medical Device Technologies, University of Texas School of Public Health, Dissertation (2010).
- Regulatory Professional Development, Presentation, Baylor College of Medicine (2008)
- Overview of Medical Device Process, Presentation, Food & Drug Law Course, University of Houston (2008).
- Supplement for Food & Drug Law Course, University of Houston (2000, 2001, 2002)
- *Medical Device Advertising and Promotion*, Presentation, Regulatory Affairs Professional Society (2000).
- *The Regulatory Professional and the Internet*, Publication, Regulatory Affairs Professional Society (1999).
- *EC New Directives & Medical Devices*, Presentation, International Society of Quality Assurance (1993).